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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/082,415	02/26/2002	Michael J. Pugia	017191.0003 (MSA-2645)	8582

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SIEMENS CORPORATION
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EXAMINER	
SIEFKE, SAMUEL P	
ART UNIT	**PAPER NUMBER**
1797	

MAIL DATE	DELIVERY MODE
12/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/082,415	PUGIA ET AL.	
	Examiner	Art Unit	
	Samuel P. Siefke	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-13,16-18 and 38-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,5-13,16-18 and 38-50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 38 are rejected under 35 U.S.C. 102(b) as being anticipated by Shartle et al. (USPN 5,230,866).

Shartle discloses a sample well (cavity) for receiving a portion of liquid sample (figure 5, ref. 110; col. 14, line 64- col. 14, line 15), a hydrophilic capillary passageway (fig. 5, ref. 120; col. 22, line 20-30) communication with the sample well (col. 15, line 30-co. 16, line 24), a capillary passageway (measuring capillary) segment having a predetermined volume and which operates to measure and hold a portion of the sample for dilution (fig. 5, ref. 140a; col. 15, lines 30-col. 16, line 24), the segment being defined between two vents which vent to the atmosphere (v1 is 110 and v2 is 104; col. 18, lines 25-57 discusses multiple vents, col. 8, lines 45-67 vents to atmosphere),a hydrophilic transfer capillary (the capillary segment seen in fig. 5 between ref. 147(capillary stop) and the intersection of capillaries of 120 and 140a) for transferring said uniform volume of said liquid from the segment defining said uniform volume of said liquid sample being between two vents to a first well (fig. 5, ref. 140, col. 17, lines 62-col. 18, line 2, col. 21, lines 1-25), a hydrophilic capillary stop (fig. 5, ref. 147) disposed within the transfer

hydrophilic capillary passageway for preventing transfer of the sample until the resistance is overcome by a means for applying force other than centrifugal force (venting of internal gases allows for the resistance to be overcome and allow the sample to pass the capillary stop, col. 9, lines 3-50).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to

consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 5-13,16-18 and 38-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over McNeely et al. (USPN 6,296,020) in view of Kellogg et al. (USPN 6,063,589) and in further view of McNeely et al. (USPN 6,615,856).

McNeely '020 teaches a fluid circuit that is based upon passive fluid dynamics. McNeely device comprises a plurality of sample well (fig. 3a-3d) a hydrophilic capillary passageway that is in fluid communication with sample well (col. 3, lines 35-37; col. 5, lines 39-41; capillary channel is hydrophilic when non-polar solutions are employed), the passageway including a segment defining a volume of a liquid sample, the segment disposed between two vents to the atmosphere (col. 4, lines 8-10; col. 4, lines 50-55; fig. E-G; col. 9, lines 19-60; col. 11, lines 1-16), a hydrophilic capillary stop disposed within the hydrophilic capillary passageway for preventing sample transport until the resistance of the stop is overcome by a force other than centrifugal force (col. 5, lines 50-59; col. 6, lines 11-47; col. 8, lines 64-68; col. 9, lines 3-14).

McNeely does not specifically teach a device in which liquid flows by capillary action from a sample well into a segment that defines sample volume.

McNeely teaches micro channels is defined herein to be a channel having a diameter of from 0.1 to 1000 microns" then goes on to demonstrate capillary action (col. 5, lines 30-49). Because McNeely defines a specified microchannel diameter being between 0.1 to 1000 microns, these size channel diameters inherently have capillary action when a liquid is present. Thus, the reason McNeely provides capillary stops, so

liquid does not travel throughout the microchannel unimpeded. Capillary stops are provided to move fluids through microchannels in a controlled fashion and are discussed throughout McNeely. As seen in figures 8a-8c, sample fluid flows into wells or channels and is stopped at a known location due to the use of stopping means (FIG. 8A, stopping means exist at the right of each of the 4 initial wells between each well and the exiting microchannel). Air or another gas is pushed through the ports (appearing as holes to the left of the 4 initial wells in FIGS. 8A-C) into the fluid channels. The air will displace the fluid downstream past the stopping means (FIG. 8B), and in this case, into the consolidation well (FIG. 8C). Air escape ducts in the consolidation well allow displaced air to exit the system so fluid can fill the consolidation well.

Kellogg teaches a sample chamber in fluid communication with a plurality of metering capillaries and an overflow channel. A sample is applied to sample chamber well where it flows into the metering capillaries (by centripetal force). The excess flows in the overflow channel and is discarded. At the end of the metering capillaries is a capillary stop (centripetal forces are used to overcome the stop). It would have been obvious to one having an ordinary skill in the art at the time of the invention to modify McNeely to employ the metering capillaries of Kellogg in order to meter a certain volume of sample for analysis into the metering capillaries. This would provide a precise volume of sample for analysis which is commonly routine and known in the art. It would be recognized that capillary action would move the fluids of McNeely into the metering chambers (provided by Kellogg) because McNeely does not employ a centrifuge for movement of fluids. A hydrophilic stop would be employed at the end of

the metering capillaries to stop the fluid entering the capillary of which would be overcome by the addition of air into the ports as seen in figure 8b.

Further Kellogg teaches reagent wells that contain a reagent adapted to react with a component contained in the sample and produce a response indicating the amount of component in the liquid sample (col. 14, lines 5-34) along with reducing the interference of the component with a second component to be detected (col. 17, lines 5-20). The first reagent well contains a reagent to pretreat the liquid sample (col. 17, lines 5-20). Electrodes are disposed in the reagent wells for measuring properties of the liquid sample (col. 53, line 66- col. 54 line 29). It would have been obvious to one skilled in the art to modify McNeely to employ an electrode to measure a property of a fluid because it is well known in the art that microfluidic devices are used for mixing samples with reagents and detecting a reaction product.

McNeely '856 discloses a device for regulating the movement of fluids through a microfluidic circuit by combining passive and active control methods to utilize an air vent (or air duct) in support of a capillary barrier in cooperation with a capillary stop junction. In this device, the fluid flows through a capillary channel and is primarily controlled by a capillary stop junction. The reliability of the capillary stop junction is increased by the addition of an air vent. The fluid is drawn through the microfluidic circuit by positive capillary forces, such as aqueous fluids being drawn by capillarity through a hydrophilic channel. When the air vent is closed, the air vent supports the capillary barrier at the capillary stop junction to control the advancement of fluid through the microfluidic circuit. Because the air vent supports a capillary barrier, this method of fluid control will not

function independent of a capillary junction (col. 1, line 60- col. 2, line 9). McNeely provides this in the background of the invention. Therefore it would have been obvious to one having an ordinary skill in the art at the time of the invention to modify McNeely to employ passive and active control methods to utilize an air vent (or air duct) in support of a capillary barrier in cooperation with a capillary stop junction because the reliability of the capillary stop junction is increased by the addition of an air vent which provides better control of a fluid within a capillary channel.

Response to Arguments

Applicant's arguments filed 10/15/07 have been fully considered but they are not persuasive. Applicant argues, "Shartle shows a sample inlet but it can be merely an opening and it is not a sample well shown by the applicants." The sample wells 110 of the Sharle is structurally capable of receiving a sample and there fore is a sample well for collecting a sample to be processed.

Applicant argues, "147 is a closed rupture junction and 145 is not vented because 104 is closed to assist 145." The Examainer above has stated that the hydrophilic capillary passageway as seen in fig. 5, ref. 120 is in communication with the sample well 110.

Applicant argues, "it is not clear that the segment is defined, since valve 202 is used to rupture junction 147, which said to dispose of excess sample into 148. The segment appears to be 140a and 140b which is not define as being between two vents.

The Examiner would like to point to figure 5 where a sample well 110 is seen. The Examiner submits that since the sample well is open to the atmosphere it can be a vent (vent 1). The capillary passageway 120 and uniform volume segment 140a are located between the vent 1 (110) and a second vent 104 that vents to the atmosphere. A vent in these types of device is any opening in a fluid capillary that is vented to the surrounding atmosphere. Vent 1 and vent 2 as the Examiner has described are proper vents as described in the instant claims. Therefore Shartle discloses a uniform volume between two vents to the atmosphere.

Applicant argues, "Shartle's device does not provide a transfer capillary from his measuring chamber 140)." The Examiner maintains that the transfer capillary is the segment located between ref. 147 (capillary stop) and the intersection of capillary 120 and 140a (measuring capillary) as seen in figure 5. This is a capillary that exits the capillary of 120 and 140a and provides a sample to well 140. Therefore Shartle discloses a transfer capillary. The Examiner would like to remind the applicant that the claims are directed to a device and the references need only show a structure that is capable of performing the instant application invention. Further the transfer capillary is between vent 1 and vent 2 as described above.

Applicant argues, "Shartle has no transfer passageway and thus has no capillary stop in the passageway." The Examine points to the previous paragraph for the interpretation of the transfer capillary of Shartle. The capillary stop is seen in figure 5 as reference 147.

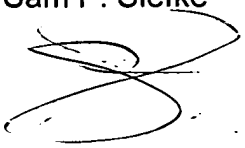
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Samuel P. Siefke whose telephone number is 571-272-1262. The examiner can normally be reached on M-F 7:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on 571-272-1700. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sam P. Siefke



December 21, 2007